# This Page Is Inserted by IFW Operations and is not a part of the Official Record

### **BEST AVAILABLE IMAGES**

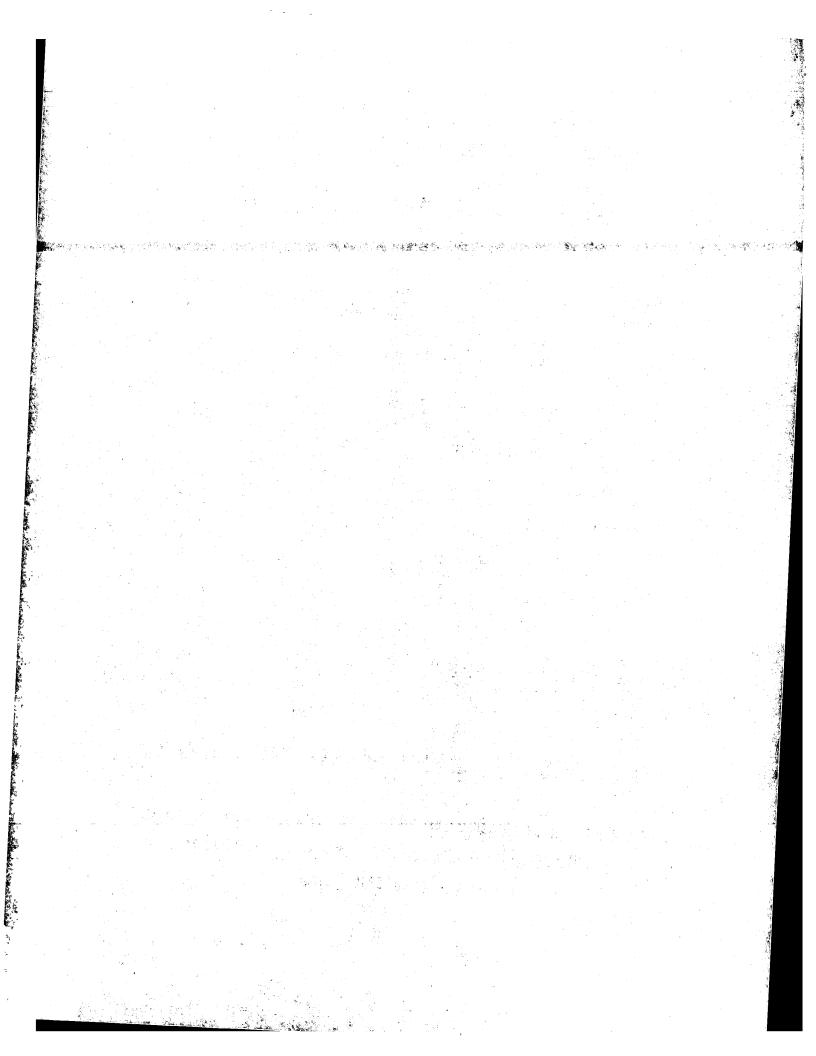
Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

## IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.



### WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



#### INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classificati n 5:

A61B 19/08

(11) International Publication Number: WO 90/06731

(43) International Publication Date: 28 June 1990 (28.06.90)

(21) International Application Number: PCT/US89/05590

(22) International Filing Date: 14 December 1989 (14.12.89)

(71) Applicant: KIMBERLY-CLARK CORPORATION [US/US]; 401 North Lake Street, Neenah, WI 54956 (US).

16 December 1988 (16.12.88) US

(72) Inventor: GRIER-IDRIS, Carletta; 1362 Meadow Creek Way, N.W., Acworth, GA 30101 (US).

(74) Agent: WILSON, Patrick, C.; Kimberly-Clark Corporation, 401 North Lake Street, Neenah, WI 54956 (US). (81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, SE (European patent).

#### Published

With international search report.

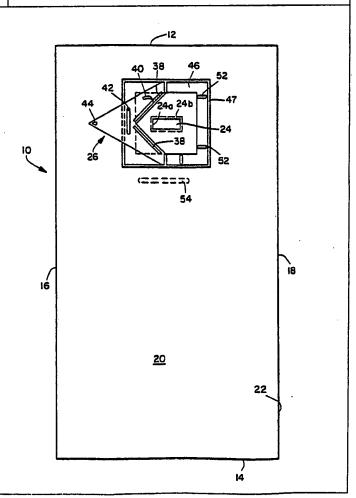
(54) Title: BI-LATERAL SURGICAL DRAPE

#### (57) Abstract

(30) Priority data:

285,471

A fenestrated surgical drape (10) is disclosed which has a fluid collection pouch (26) pivotally attached about the fenestration so that the pouch may be selectively attached to either side of the fenestration. As a result, the same surgical drape may be used for either right- or left-handed procedures.



# FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

	and I CI.			our bages of	pampi	niels publishing inter
AT AU BB BE BF BG BJ BR CA CF CG CH	Austria Australia Barbados Belgium Burkina Fasso Bulgaria Benin Brazil Canada Central African Republic Congo	ES FT FR GA GB HU IT JP KP	Spain Finland France Gabon United Kingdom Hungary Italy Japan Democratic People's Reput of Korea		MG ML MR MW NL NO RO SD SE	Madagascar Mali Mauritania Malawi Netherlands Norway Romania Sudan Sweden Seneral
	Congo Congo Switzerland Cameroon Germany, Federal Republic of Denmark	KR LI LK LU MC	of Korea Republic of Korea Liechtenstein Sri Lanka Luxembourg Monaco		SN SU TD TG	

PCT/US89/05590

5

10

15

20

25

30

35

#### BI-LATERAL SURGICAL DRAPE

#### BACKGROUND OF THE INVENTION

The present invention relates to a new and improved surgical drape with a fluid collection system. More specifically, the drape of the present invention is fenestrated and has a reversibly-attachable fluid collection pouch which may be selectively secured to either side of the fenestration. The reversibility of the pouch allows the surgical team to adapt the drape for use on either side of the fenestration.

Surgical drapes with fenestrations are well known in Many such drapes are often used in surgical procedures where fairly large amounts of body fluids or irrigation liquids are emitted from the fenestrated operating site. Numerous means have been developed to absorb, retain and/or collect such fluids. Early surgical procedures often involved the use of absorbent towels to square off the operating site. These towels would in turn act to absorb fluids. Gradually, the designs were improved to include absorbent materials built into the drape itself, including such materials located as foam about fenestration. When large amounts of fluid were being used or emitted from the incision area, bags and other types of drainage apparatus were employed to channel, collect or drain the fluids away from the operating site. Examples of such systems can be found in neurological, obstetrical (c-section) and orthopedic (arthroscopy) drapes.

Many of today's surgical drapes are customized to be compatible with specific procedures such as neurological, obstetric, orthopedic, cardiovascular and opthamic procedures. Several procedures such as eye, abdominal, limb and back surgery may be performed on either the right-or the left-hand side of the body, depending upon the ailment or injury. As a result, many of these customized

10

25

30

35

drapes be stocked either right-handed in left-handed models to accommodate the specific procedure or else a more expansive cumbersome design must be used to cover all options. It is therefore an object of the present invention to provide a surgical drape design which will reduce the need for such duplicate stock.

Another reason for the need to inventory both leftand right-handed stock is the fact that certain operating room designs, as well as the preferences of certain surgeons, dictate that a procedure be performed from either the left or the right side of the patient. Consequently, there is a further need for surgical drape designs which are more universal in their application.

Certain surgical drapes, such as Collins (U.S. Patent 3,791,382), disclose surgical drapes for abdominal 15 surgery with pouches on either side of the incision area. Typically, however, to the extent possible fluid will be directed to the pouch on the side of the table opposite the surgeon. This is because during the procedure the surgeon will oftentimes lean up against the side of the operating 20 table in which case contact with the fluid-filled pouch on the surgeon's side of the table may cause the pouch to collapse, thereby causing the fluid to run out over the surgeon and the operating floor. This provides potentially hazardous situations due to slipping, electrical shock and infection. Conversely, certain ophthalmic drapes, such as the Surgikos Phaco extracapular pack #1226 by the Johnson and Johnson Company, provide a fluid collection pouch in the surgical pack which is initially detached from the surgical drape. Once the drape is in place, the pouch is drape in close fenestration on either the right- or left-hand side of the proximity drape. Having the pouch initially detached from the drape is not a desirable feature to some operating room personnel as it increases the number of items which must be accounted for at the end of the surgical procedure. The present

invention is an improvement over the above-discussed surgical drape design, in that it provides an attached fluid collection pouch which may be selectively pivoted and adhered to either side of the fenestration. This feature also provides improved turn around time in high volume procedures such as opthalmic surgeries. A further understanding of the present invention may be gained from a more detailed review of the following specification, drawings and claims.

10

15

20

25

5

#### SUMMARY OF THE INVENTION

The present invention relates to a bi-lateral surgical Attached about fenestrated. the which is drape fenestration is a fluid collection pouch which may be pivoted and selectively secured to either side of the The reversibility of the pouch allows the fenestration. surgical team to adapt the drape for use on either the left- or right-hand side of the fenestration. To secure the pouch to the drape, the drape is also supplied with double-sided adhesive tape. In addition, to control fluid run-off from the fenestration, the surgical drape may also include a fluid trough extending at least partially or preferably entirely around the fenestration. During use, the open side of the fluid trough creates a channel about the exterior of the fenestration to collect any stray fluid run-off.

#### BRIEF DESCRIPTION OF THE DRAWINGS

30

35

Figure 1 is a top plan view of the bi-lateral surgical drape of the present invention.

Figure 2 is an enlarged view of the fluid control pouch of the drape shown in Figure 1 according to the present invention.

Figure 3 is a cross-sectional view of the fluid control system taken along line 2-2 of Figure 2.

# DESCRIPTION OF THE PREFERRED EMBODIMENTS

5

10

15

25

30

35

The surgical drape will now be described in conjunction with its design and use in ophthalmic surgery. In particular, as will be described below, the novel features of the present invention will allow the operating team to use one drape and elect whether to use the fluid collection pouch on either side of the fenestration depending upon the needs of the procedure. understood, however, that the description of the present It should be invention in conjunction with its use in an ophthalmic drape is for illustration purposes only. Drapes designed for other surgical procedures which embody the present invention are also considered to be within the scope of the appended claims.

Referring now to Figure 1, there is shown a drape or mainsheet 10 including a top edge 12 and a bottom edge 14 20 joined by a pair of opposed side edges 16 and 18 thereby defining a top surface 20 and a bottom surface 22 with a fenestration 24 located interiorly therein. design such as an ophthalmic drape the dimensions should generally be from about 70 to 140 inches long with a width of from about 50 to 70 inches. Most typically, fenestration 24 having opposed sides 24a and 24b is centrally located from the side edges 16 and 18. addition, the fenestration 24 is located approximately 30 inches from the top edge 12 so there is sufficient material on the drape 10 to extend down over the head of the patient in one direction and as far as the patient's knees or lower in the other direction.

The drape 10 may be made from any number of materials such as cloth, nonwovens (spunbonds, meltblowns, bonded carded webs, etc.), plastic films or a combination of the

. 10

15

20

25

30

35

foregoing. In preferred embodiments, the drape 10 is fluid-impervious at least about the fenestration site 24 to prevent fluid strike-through. It is particularly important that ophthalmic drapes be fluid-impervious since certain procedures are performed while the patient is awake. It is also preferred that the material, in addition to being fluid-impervious, be breathable to enhance patient comfort. One such material which provides these attributes is a spunbond/meltblown/spunbond laminate manufactured by the assignee of record, Kimberly-Clark Corporation, and sold under the trademark "EVOLUTION".

Pivotally attached about its opening to the surface 20 of the drape 10 is a fluid collection pouch 26. Referring to Figure 2, the fluid collection pouch 26 is formed from a first sheet 28 and a second sheet 30 having commonly joined side edges with open top edges (28a, 30a) thereby defining a fluid receiving chamber 32. Each of the top edges 28a and 30a are cut out inwardly toward the bottom of the pouch 26 such that they will not overlap the fenestration 24. The junctures of the top (28a, 30a) and side edges are permanently secured to the top surface 20 of the drape 10 be securing means 34 such as adhesive tape, hot melt adhesive or heat sealed joints, for example. Attachment of the pouch 26 to the drape 10 should be in such a fashion that the pouch can be selectively pivoted about the secured area to either side of the fenestration 24 as shown by the arrow 36 in Figures 2. In either position, it can be seen that the open top edges 28a, 30a of the pouch 26 do not interfere with or overlap the fenestration 24.

To secure the pouch to the drape 10, both the first and second sheets 28 and 30 of the pouch 26 are provided with fastening means 38 directly adjacent their top edges 28a and 30a. Most preferably the fastening means 38 are double-sided adhesive tapes with release paper 40 on the sides opposite those affixed to the pouch 26. Thus, if the

10

15

20

25

30

35

pouch 26 is to be affixed to the right side of the fenestration 24, the fastening means 38 is used to secure the first sheet 28 to the right side of the fenestration 24. Conversely, if the pouch is to be affixed to the left side of the fenestration 24, the fastening means 38 located on the second sheet 30 is used to secure the second sheet 30 to the left side of the fenestration 24. Alternatively, the fastening means 38 may be initially attached to the drape 10 instead of the pouch 26 and used to secure the pouch 26 to either side of the fenestration 24. As a result, the drape 10 may be used to selectively channel and collect fluids from either side of the drape 10 by simply pivoting and adhering the pouch 26 to the proper side of the drape 10.

To keep the pouch open to receive fluids, the first and second sheets 28 and 30 may be fitted with malleable strips 42 adjacent the respective top edges 28a and 30a which may be hand-formed to keep the pouch 26 open to properly receive fluids. The malleable strips 42 may be made from soft metal with or without plastic coating and secured to the inside or outside of first and second sheets 28 and 30.

The fluid collection pouch 10 also may be fitted with a drain fitting 44 adjacent the lowermost position of the fluid receiving chamber 32 to allow for the drainage of collected fluids from the pouch 10. Most typically the drain fitting 44 is connected to flexible tubing (not shown) which is fed into a fluid receptacle such as a bucket (not shown) to collect the drained fluids.

To further control fluid run-off from the fenestration 24, the surgical drape 10 may also include a fluid trough 46 extending at least partially or preferably entirely around the fenestration 24 as shown in Figures 1 and 2 and in cross-section in Figure 3. The outer most edge 47 of the trough 46 may be secured to the top 20 of the surgical drape 10 by such means as heat sealing or adhesive so as to

form a fluid tight seal about its periphery. In addition, the material for the fluid trough 46 should be fluid impermeable so as to contain fluids. During use, the open side 48 of the fluid trough 46 creates a channel 50 about the exterior of the fenestration. To help keep the channel 50 open, the fluid trough 46 may be fitted with malleable opening strips 52 similar to those described in conjunction with reference numeral 42 to keep the fluid trough in an open position.

Lastly, the drape or mainsheet 10 may also be fitted with malleable strips 54 similar to those discussed above. Most preferably such strips 54 would be fitted to the mainsheet 10 in the area overlying the nose and mouth region of the patient to lift the mainsheet off the patient's face to facilitate breathing.

Having thus described the invention in detail, it should be appreciated by those skilled in the art that various modifications may be made in the present invention without departing from the scope and spirit of the following claims.

10

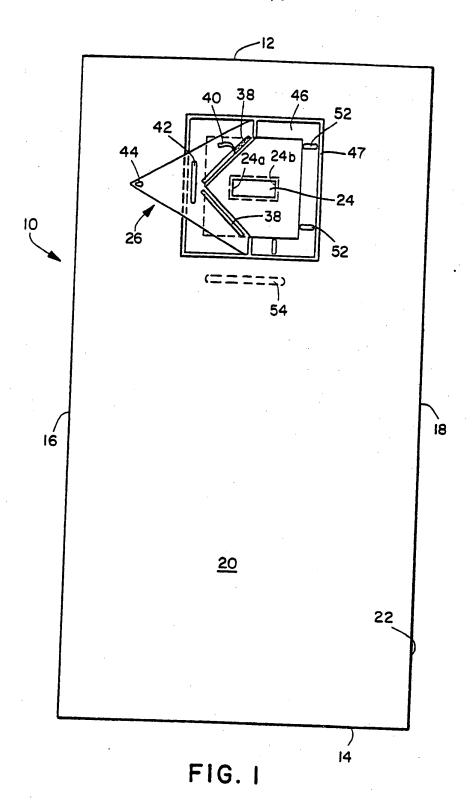
15

#### WE CLAIM:

### A surgical drape comprising:

- a mainsheet including a top edge and a bottom edge joined by a pair of opposed side edges, thereby defining a top surface and a bottom surface, with a fenestration located therein, said fenestration having opposed sides, and
- a fluid collection pouch formed from a first sheet and a second sheet having commonly joined side edges and open top edges, thereby defining a fluid receiving chamber therein, and releasably fastenable fastening means located on said first and second sheets of said fluid collection pouch adjacent said open top edges, said fluid collection pouch being pivotally attached to said drape adjacent said fenestration whereby said pouch may be selectively pivoted and secured to said drape or either of said opposed sides of said fenestration using said fastening means thereby trapping and collecting fluid run-off from said fenestration.
- 2. The surgical drape of claim 1 wherein said fluid collection pouch contains malleable opening strips attached to said fluid collection pouch adjacent said open top edges for keeping said top edges in an open position.
- 3. The surgical drape of claim 2 wherein said fluid collection pouch is fitted with a drain fitting.
- 4. The surgical drape of claim 1 wherein said fluid collection pouch is fitted with a drain fitting.
- 5. The surgical drape of claim 1 wherein said fastening means are initially located on opposed sides of said fenestration so as to secure said open top edge to said top surface of said drape.
- 6. The surgical drape of claim 1 wherein said top surface of said drape has secured thereto a fluid trough which at least partially surrounds said fenestration for trapping fluids.

7. The surgical drape of claim 5 wherein said top surface of said drape has secured thereto a fluid trough which at least partially surrounds said fenestration for trapping fluids.



westillisens

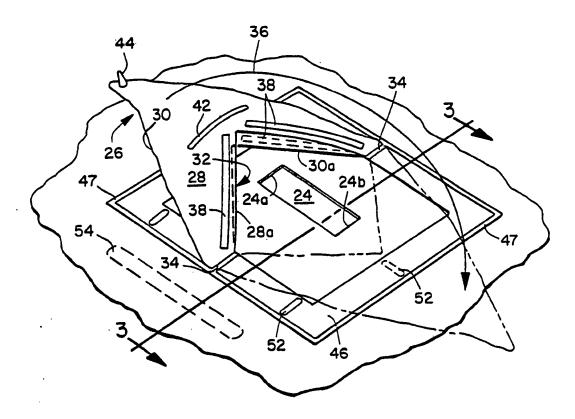


FIG. 2

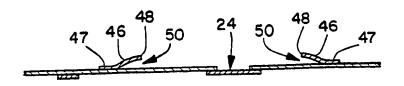


FIG. 3

# INTERNATIONAL SEARCH REPORT

1	LASSIFICATION OF SUBJECT MATTER (if seven ording to International Patent Classification (IPC) or to	both National Classification and IRC	<u> </u>
l	H OI B 19/08	and IPC	
11. 5	ELDS SEARCHED		
Ciass	fication System 1	Documentation Searched 7	
	TOTAL SYSTEM 1	Classification Sympols	
IPC	5 A 61 B	STATE OF SYMBOLS	
	Documentation Searcher	d other than Minimum Documentation	
	to the extent that such Doc	s other than Minimum Documentation cuments are included in the Fields Searched 4	
	¥		·
III. DO	CUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of Document, 11 with indicates		
Y	Citation of Document, 11 with indication, whe	re appropriate, of the relevant passages 12	Relevant to Claim No. 13
	US, A, 4196723 (MOOSE, see column 3, lines	Jr) 8 April 1980	j
1	see column 3, lines	35-45; figures	1-7
Y	US, A. 3650267		!
1	US, A, 3650267 (ANDERSON see column 2 lines	1) 21 March 1972,	11-7
ľ	see column 2, lines figures	15-23, 69-75;	- '
7	•		
A	US, A, 3791382 (COLLINS) see claim 1; figures	12 February 1074	İ
	see claim 1; figures	12 rebidary 19/4,	1
	(cited in the application	n)	
Α			
	US, A, 4089331 (HARTIGAN see claim 1; figures	et al.) 16 May 1978.	1
-			
A	US, A, 4596245 (MORRIS)	24 Tune 1006	
į		24 odue 1988	
			•
į		~~~~	
:	•		
ĺ		·	
. i			
1			
		ļ	1
"A" docum	stegories of cited documents; 19	"T" lates de	
Consi	ered to be of particular release of the art which is not	"I" later document published after the or priority date and not in conflict cited to understand the principle of	international filing date
filing	gocument but published on or after the international	INAGUITOR	agi) nugetiying the !
"L" BOCUR	ent which may throw doubts on pringly claimte)	"X" document of particular relevance; cannot be considered novel of ca involve an inventive step	the claimed invention
		"Y" document of particular	considered to
other	leans to an oral disclosure, use, exhibition or	"Y" document of particular relevance; cannot be considered to involve an document is combined with one or	
	int published prior to the international filing date but	document is combined with one or ments, such combination being obvi in the art.	more other such docu-
CERTIF	ATION	"4" document member of the same pate	nt family
te of the A	tual Completion of the International Search		
7th M	arch 1990	Date of Mailing of this International Search	Report
		2 7. 03. <b>90</b>	
	Parching Authority		
E	ROPEAN PATENT OFFICE	Signature of Authorized Officer	

# ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

US 8905590 SA 33239

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 20/03/90
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document Publication Patent family Publication cited in search report date member(s) date US-A- 4196723 08-04-80 CA-A-1137848 US-A- 3650267 21-03-72 None US-A- 3791382 12-02-74 CA-A-1005302 15-02-77 CA-A-1004938 08-02-77 CA-A-1020830 15-11-77 US-A- 4089331 16-05-78 CA-A-1092465 30-12-80 US-A- 4596245 24-06-86 AU-B-576045 11-08-88 AU-A-5220086 16-07-87 CA-A-1253047 25-04-89 EP-A,B 0191296 20-08-86 JP-A-61181458 14-08-86

